Remarks

Claims 1 and 23-26 are pending and under consideration. With this Amendment, Claims 1 and 23-26 are being cancelled, without prejudice against their reintroduction into this or one or more timely filed continuation, divisional or continuation-in-part applications, and claims 27-32 are being newly added. Thus, after entry of this Amendment, claims 27-32 are pending and under consideration. The amendments of the claims and the various rejections raised in the Office Action are discussed in more detail below.

I. Amendments of the Claims

Claims 1 and 23-26 have been cancelled and replaced with claims 27-32. Basis for the claims are as follows.

Claims 27 and 28 are supported throughout the specification, such as on page 2, lines 20-32; page 9, line 13 through to page 10, line 13; Example 3; and claims 1 and 3 as originally filed.

Claims 29-32 are supported in the specification on page 9, line 13 through to page 10, line 13; and original claims 10-13.

No new matter is entered by way of the amendments. Entry is therefore respectfully requested.

II. Finality of the Restriction Requirement

As a preliminary matter, the Office Action provides that if prior claim 1 is found allowable, the claims of inventive Group II will be rejoined and examined on the merits. Applicant thanks the Examiner for reiteration of this aspect of the restriction, and kindly requests the same treatment for the currently pending claims.

With regards to the restriction requirement, the Patent Office has made final the restriction of September 9, 2006. It appears the underlying basis of the Patent Office's justification for the restriction in this case, as compared to the parent case, is based, in part, on the alleged lack of priority of the claims to parent application serial no. 09/402,845. Applicant disagrees with this basis for the restriction.

First, Applicant wishes to clarify that the arguments made in the response to the restriction merely set forth the proposition that no undue burden would arise from concurrent examination of the claims of inventive Group I and inventive Group II given that a search and examination of the claims of Group II had been carried out in the parent application.

Second, the issue raised by the Patent Office concerning sufficiency of support for the claims in the instant application and in the originally filed specification of the parent application has no role in justifying a restriction. The statement in the Office Action concerning proper support for the claims is more appropriate to different aspects of the patent statues than those involved in the restriction of claimed inventions. Restriction practice concerns the presence of more than one patently distinct inventions in a single application. The point the Patent Office appears to be making for the inapplicability of the search and examination of the claims carried out in the parent application to the instant application is, in part, the asserted difference between the scope of the claims in the instant application and the scope of the claims examined in the second application. Applicant notes that this reasoning does not involve sufficiency of support. For the record, it is Applicant's position, as further discussed below, that the claims presented in the instant application are sufficiently supported by the specification of application serial no. 09/402,845. In light of the rationale set forth by the Patent Office, Applicant traverses the finality of the restriction requirement to preserve the right of petition under 37 C.F.R. § 1.144.

III. Priority

The Patent Office contends that prior claim 1 is not adequately supported by the specification of the parent application serial no. 09/402,845. Specifically, the Patent Office acknowledges adequate description for an isolated polypeptide comprising a polypeptide with at least about 90% sequence identity to the sequence of SEQ ID NO:2, which can be made by conservative amino acid substitutions where the conservative substitutions do not alter the sequence by more than 10%. However, the Patent Office contends that there is insufficient basis for an isolated peptide that is immunoreactive with an antibody that is itself immunoreactive with human PAP.

As discussed below, a review of the original specification on page 2, lines 23-26 states that the polypeptides can be used as an antigen to produce a humoral and/or cellular response against tumor antigens present in a subject. Inducing an immune response against human prostatic acid phosphatase using the claimed polypeptides is specifically described throughout the specification, such as on page 3, lines 5-6. Moreover, the original specification states that immunization of mice with either rat, mouse, or human PAP resulted in production of antibodies that reacted with all three antigens. *See* Specification, page 9, lines 29-32. Thus, the isolated polypeptide of SEQ ID NO:2, which is the sequence of an isolated mouse PAP, was immunoreactive with antibodies immunoreactive with human PAP. Therefore, prior claim 1 is adequately supported by the original specification.

Nevertheless, it is submitted that pending claims 27 and 28 obviate the priority issue as the claims are sufficiently supported by the as filed specification of the parent application.

IV. Objections

The specification is objected to for allegedly failing to provide proper antecedent basis in the specification for the subject matter of prior claim 1. Applicant respectfully disagrees.

An objection based on improper antecedent basis of the claims arises in cases where the *claims as originally filed* are not disclosed in the remainder of the specification. *See* M.P.E.P. § 2163.06. Because the original claims are part of the disclosure, an applicant is afforded the opportunity to amend the specification based on the claims as filed. However, a claimed invention need not be described *ipsis verbis* in the specification in order to satisfy the disclosure requirements for patentability. *See Ex part Holt*, 19 USPQ2d 1211 (BPAI 1991); *see also* M.P.E.P. § 2163. For prior claim 1 and the currently pending claims, the specification describes on page 2, lines 26-31 and page 7, lines 29-32 that the isolated polypeptide can comprise a polypeptide with at least about 90% sequence identity to the sequence of SEQ ID NO:2, which can be made by conservative amino acid substitutions, where the conservative substitutions do not alter the sequence by more than 10%. Further, the specification on page 2, lines 23-26 states that the polypeptides can be used as an antigen to produce a humoral and/or cellular response against tumor antigens present in a subject. Inducing an immune response using the claimed polypeptides against human prostatic acid phosphatase is specifically described throughout the specification, such as on page 3, lines 5-6. Thus, the language used in prior claim 1 and the currently pending claims is found in the instant application such that there is sufficient antecedent basis in the specification for the claims. Therefore, reconsideration and withdrawal of the objection is respectfully requested.

V. Rejections under 35 U.S.C. § 101

Claim 1 is rejected under 35 U.S.C. § 101 because the claim is allegedly inoperative and therefore lacking in utility. Applicant traverses the rejection as applied to pending claims 27 and 28.

The rejection for lack of utility rests on a claim construction in which the isolated peptide is to a human prostatic acid phosphatase. However, the specification and original claims clearly recite an isolated polypeptide which has at least 90% amino acid sequence identity to SEQ ID NO:2, which is the sequence of a prostatic acid phosphatase isolated from mouse. As explained in the specification, the isolated polypeptides are useful in eliciting an immunologic response, which includes both humoral and cell mediated immune response, against human prostatic acid phosphatase, a known tumor antigen in prostate cancer. Consequently, the claimed polypeptides have at least one specific, credible and substantial utility.

In this Amendment, Applicant has amended the claims for technical clarity such that claim 27 recites an isolated polypeptide immunologically crossreactive with human prostatic acid phosphatase, where the isolated polypeptide comprises at least 90% amino acid sequence identity to SEQ ID NO:2. In light of use of the polypeptides described in the specification, the isolated polypeptides encompassed by the pending claims have the requisite utility under 35 U.S.C. § 101. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

VI. Rejections under 35 U.S.C. § 112, first paragraph

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. The Patent Office contends that while the specification is enabling for an isolated peptide of SEQ ID NO:2, it does not enable an isolated variant having at least 90% identity to SEQ ID NO:2.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description. The Patent Office contends that a variant having 90% sequence identity to SEQ ID NO:2 does not satisfy the written description standards enunciated in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem., Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002).

Applicant respectfully traverses the rejections as applied to claims 27 and 28.

A. Enablement

1. Legal Standard for Enablement

The standard for determining enablement under first paragraph of 35 U.S.C. §112 is whether the specification enables any person skilled in the art to which it pertains to make and use the claimed invention without undue experimentation. *See, e.g., In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *See In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *see also* M.P.E.P. § 2164.0.

Moreover, a considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed. *See Ex parte Forman*, 230 USPQ 546, 547 (BPAI 1986); *see also In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). The fact that the required experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *See MLT. v A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

2. Enablement is Commensurate with the Scope of the Claims

When rejecting a claim under the enablement clause of 35 U.S.C. § 112, first paragraph, the Patent Office bears the initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by that claim is not adequately enabled by the description of the claimed invention provided in the specification of the application. *See* M.P.E.P. § 2164.04. In attempting to meet this burden, the Patent Office construes the claim to require only a single antibody having cross-reactivity to the claimed polypeptide and human prostatic acid phosphatase, and contends that since an antibody recognizes a minimal epitope size of 5 amino acids, any isolated peptide having 1% identity to SEQ ID NO:2 is encompassed by the claim. However, as further discussed below, this construction is unreasonable since it limits the entirety of the claim based on an antibody reactive with the claimed polypeptide and human prostatic phosphatase, and disregards the limitation of the isolated polypeptide being at least 90% identical in amino acid sequence to SEQ ID NO:2. Claims must be viewed in its entirety and requires consideration of all claim limitations in light of and consistent with the written description. *See, e.g., In re Ochai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). The claimed invention must not be dissected into discrete elements to be analyzed in isolation, but must be considered as a whole. *See WL. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983). When viewed in its proper context, the scope of the claims under examination is directed to an isolated polypeptide immunologically crossreactive with human prostatic acid phosphatase, where the isolated polypeptide has at least 90% amino acid sequence identity to SEQ ID NO:2. This excludes a polypeptide having 1% sequence identity to SEQ ID NO:2.

Having addressed the breath of the claims, Applicant notes that the specification provides a representative embodiment of the claimed polypeptide, namely a prostatic acid phosphatase isolated from mouse, falling within the scope of the claims. This embodiment is immunologically crossreactive with human prostatic acid phosphatase in

that it can produce humoral and cell mediated immunological responses to human prostatic acid phosphatase protein as well as cells that express human PAP. As described in the specification, sequences of at least two other forms of prostatic acid phosphatase were available to the skilled artisan at the filing date. These include human and rat forms of the polypeptide. The specification states that the amino acid *sequence identity* between human and rat is 78%, between human and mouse is 80%, and between rat and mouse is 87%, which emphasizes the high degree of sequence conservation between those mammalian species. Because of the sequence conservation between prostatic acid phosphatase identified in evolutionarily divergent animals, a person skilled in the art could readily identify sequences conserved between the human prostatic acid phosphatase and the polypeptide of SEQ ID NO:2 and determine the amino acid residues that can be altered without affecting the immunological crossreactivity of the claimed polypeptide and human prostatic acid phosphatase. It is submitted in view of the 80% amino acid sequence identity between human prostatic acid phosphatase and mouse prostatic acid phosphatase that a person skilled in the art can alter least 20% of the amino acids in the mouse prostatic acid phosphatase and maintain its immunologic crossreactivity with human prostatic acid phosphatase, particularly given the position of the Patent Office that an epitope recognized by an antibody is about 5 amino acids. Similarly, in light of the sequence conservation between prostatic acid phosphatases, a person skilled in the art can also alter 10% of the amino acids in mouse prostatic acid phosphatase to have 90% amino acid sequence identity to SEQ ID NO:2 and maintain immunologic crossreactivity with human prostatic acid phosphatase.

At the filing date of the instant application, the skill in the art for comparing sequences to identify conserved regions were well known and commonly practiced (s*ee, e.g.,* Altschul et al., 1990, "Basic local alignment tool," *J.Mol. Biol.* 215:403-410). Moreover, the art typically engaged in making variant proteins, such as by introducing mutations into nucleic acids and expressing the mutated nucleic acids in host cells (*see, e.g.*, Ausubel, F.M. et al., 1992, *Current Protocols in Molecular Biology*, John Wiley and

Sons, Inc., Media, PA; and Sambrook, et al., 1989, *Molecular Cloning: A Laboratory Manual*, 2nd Ed., Cold Spring Harbor Press, Plainview, N.Y.; which are referenced in the specification on page 1). The references of Roitt et al, 1993, *Immunology*, Mosby, St. Louis, pgs 6.4-6.5 and Bost et al., 1988, *Immunol. Invest.* 17:577-586, discussed below, also show that determining immunological crossreactivity between variant proteins was routine in the art. Thus, the skill in the art for making and testing variant proteins was high at the filing date of the instant application.

Given the knowledge and skill in the art, the specification provides sufficient direction to the skilled artisan in which experimentation should proceed, which experimentation a skilled artisan would consider routine. The specification describes, in some embodiments, the types of amino acid substitutions, such as conservative substitutions, that can be made to maintain immunological crossreactivity. *See* Specification, page 5, lines 14-21; and page 7 line 28 to page 8, line 6. The specification also provides various exemplary tests for assessing immunological crossreactivity. *See* Specification, page 14, lines 3-12; and page 16, lines 22-35.

In light of the knowledge of other prostatic acids phosphatases, the high level of skill in the art for making and testing variant proteins, the description in the disclosure of an embodiment representative of the claimed polypeptides, and the amount of guidance in the specification, a person skilled in the art can predictably make and use the claimed polypeptides. In support of unpredictability in the art, the Patent Office proffers the references of Burgess et al., 1990, *J. Cell Biol.* 111(1):2129-38 and Lazar et al., 1988, *Mol. Cell Biol.* 8:1247-1252, which references are asserted to show that replacement of a single amino acid residue can affect biological activity of the involved peptides. However, Burgess and Lazar are not dispositive of predictability for the instant claims given the knowledge of conserved sequences in prostatic acid phosphatases. Applicant points out that Lazar elected to modify two amino acids *highly conserved* in EGF-like family of peptides, of which transforming growth factor alpha is a member (see, Lazar, page 1247, left column). Thus in Lazar, it was predictable that amino acid substitutions

would generate proteins with altered activity. Moreover, the pending claims recite immunological crossreactivity, while Burgess and Lazar discuss biological function of the specific proteins. Consequently, the findings of Burgess and Lazar are limited to the specific examples in those references and do not impact the unpredictability/predictability for the claimed polypeptides.

Hence, by all measures of the factors used in assessing enablement, the specification enables a person skilled in the art to make and use the claimed invention without undue experimentation. The Patent Office has not advanced sufficient objective evidence to support a case of *prima facie* nonenablement in this case. Accordingly, reconsideration and withdrawal of the rejections under the enablement clause of 35 U.S.C. § 112, first paragraph is respectfully requested.

B Written Description

1. Legal Standard

According to M.P.E.P. § 2163.02, an objective standard for determining compliance with the written description requirement is whether "the description clearly allow persons of skill in the art to recognize that he or she invented what is claimed." *See In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention. *See Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, complete or partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such

identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. *See* M.P.E.P. § 2163; *see also Univ. of Rochester v. G.D.Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886, 1894-5 (Fed. Cir. 2004).

However, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94; *see also Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. . . As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.").

2. Claims Satisfy the Written Description Standard

In supporting the rejection under the written description clause of 35 U.S.C. § 112, first paragraph, the Patent Office applies the court decisions of *Eli Lilly v. University of California* and *Enzo Biochem., Inc. v. Gen-Probe Inc.* However, subsequent decisions of the Federal Circuit have modified the application of the holdings in the two court cases. *See Falkner v. Inglis,* 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2005) (emphasis added); *see also Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005); *see also see also Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 77 USPQ2d 1161 (Fed. Cir. 2005).

Of relevance to the instant rejection is the holding in *Invitrogen Corp v. Clontech Laboratories, Inc.*, which involved claims directed to a reverse transcriptase enzyme lacking RNase H activity. The specification provided a sequence of a deleted form of the enzyme from Murine Maloney Leukemia Virus, whereas the claims covered a broad genus of modified RT enzymes, including those derived from "a retrovirus, yeast, Neurospora, Drosophila, primates, and rodents." *See Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d at 1074. The infringer asserted that the claims to the

modified enzyme was invalid under the written description clause of 35 U.S.C. § 112, first paragraph because the claims at issue were not limited to sequences recited in the specification. The Federal Circuit, however, upheld the district court's determination of adequate written description, noting the court's determination that "at the time of the invention, sequence of RT genes were known and members of the RT gene *family shared significant homologies* from one species of RT to another and that the sequences for the claimed modified enzymes and other representative RT genes were known" by the critical date. *See id* at 1073 (emphasis added). Even though sequences of the mutant enzymes for the other reverse transcriptases had not been described in the specification, the court emphasized the knowledge available to the public of the sequence of other RT enzymes, such as enzymes from HTLV-1, BLV, RSV, and HIV. The Federal Circuit concluded:

> [T]he shared written description for the patents-in-issue recites both the DNA and amino acid sequences of *a representative embodiment of the claimed RT enzyme*. The specification also discloses test data that the enzyme produced by the listed sequence has the claimed features-DNA polymerase activity without RNase H activity. Under both the *Eli Lilly* and *Fiers* analysis, the specification at bar is sufficient.

See Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d at 1073. Also relevant to the present facts is the Federal Circuit decision in *Falkner v. Inglis,* 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2005). *Falkner v. Inglis* concerned an interference involving claims encompassing a poxvirus vaccine, where the claim recited use of poxvirus with its "essential genes" deleted or inactivated. The Board of Patent Appeals and Interferences denied a motion by the junior party (Falkner) that the senior party's (Inglis) specification did not provide sufficient written description of the essential genes of the poxvirus. The Inglis application had three passages discussing poxvirus, but discussed the identity of the essential genes and their deletion only for the herpesvirus. The Inglis specification did not provide any such detail for the poxvirus, and instead, gave a general statement that the "invention can be applied to any virus where one or more essential genes can be identified and deleted from or inactivated within the virus

genome." *See id* at 1364. Despite the lack of sequences for the "essential genes" of the poxvirus and absence of any examples in the specification where such genes could be deleted or otherwise inactivated, the Federal Circuit affirmed the Board's decision of adequate written description in the Inglis' specification for poxvirus "essential genes" and thus adequate written description for the claimed poxvirus vaccine. The court noted the evidence submitted by the senior party establishing that articles describing essential genes for poxvirus were well-known in the art and that the skilled person would have been readily able to choose an essential vaccinia gene "based on references that have been publicly available." *See id.* at 1366 In view of the facts of the case, the court stated:

(1) examples are not necessary to support the adequacy of written description;

(2) the written description standard may be met even where actual reduction to practice of an invention is absent; and

(3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain recitation of a known structure.

See id. at 1366. The court noted "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either recitation or incorporation by reference (where permitted) of such genes and sequences." *See id.* Moreover, the court held:

> [It] is the binding precedent of this court that *Eli Lilly does not* set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, *regardless of whether it is known in the prior art*. . . .

See Falkner v. Inglis, 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2005) (emphasis added).

In the instant case, the sequence of homologous prostatic acid phosphatase had been described for several different mammals, including human and rat. The instant specification describes at least a third member isolated from mouse. As noted in the specification, the amino acid sequence identity between human and rat is 78%, between human and mouse is 80%, and between rat and mouse is 87%. Given the level of sequence conservation between human, rat, and mouse forms of prostatic acid phosphatase, a person skilled in the art would have readily discerned the regions conserved between the phosphatases to identity residues that could be altered without affecting the immunological cross-reactivity between the claimed polypeptides and human prostatic acid phosphatase. Moreover, as noted above, the assay for polypeptide forms falling within the scope of the claims is straightforward since methods for detecting immunological crossreactivity between proteins were well within the skill of those in the art, as evidenced by the references cited by the Patent Office (*see*, *e.g.*, Roitt et al, 1993, *Immunology*, Mosby, St. Louis, pgs 6.4-6.5 and Bost et al., 1988, *Immunol. Invest.* 17:577-586, discussed below). Applicant provides a working embodiment showing the immunological crossreactivity between the representative example of the claimed isolated peptide and human prostatic acid phosphatase. Unlike the facts in *Eli Lilly*, Applicant has disclosed a complete structure of a representative isolated polypeptide falling within the scope of the claim, which embodiment elicits an immunological response cross reactive with the human counterpart, and described two other homologs known at the time of the filing of the present application. In addition, Applicant has described a functional property, *i.e.*, immunological cross reactivity with human prostatic acid phosphatase, that correlates with the structure of the claimed isolated peptides, which property is particularly relevant in light of the sequence conservation between human, rat and mouse forms.

Since the mouse and human prostatic acid phosphatases have about 80% sequence identity, a person skilled in the art would readily recognize that at least 20% of SEQ ID NO:2 can be altered and yet still maintain the identity to human prostatic acid phosphatase and therefore be immunolgically crossreactive with the human protein. If

forms differing in 20% (i.e., having 80% sequence identity to SEQ ID NO:2) to SEQ ID NO:2 can be readily discerned by the skilled artisan, then a skilled artisan would be also be able to recognize an isolated peptide having 90% sequence identity to SEQ ID NO:2 that still retains immunological cross-reactivity with human prostatic acid phosphatase.

In view of the above, Applicant has amply satisfied the written description standard. Accordingly, reconsideration and withdrawal of the rejection under the written description clause of 35 U.S.C. § 112, first paragraph is respectfully requested.

VII. Rejections under 35 U.S.C. § 102

Claim 1 is rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by US Patent No. 5,882,864 to An et al. ("An"), as evidenced by Roitt et al, 1993, *Immunology*, Mosby, St. Louis, pgs 6.4-6.5 ("Roitt") ; and Bost et al., 1988, *Immunol. Invest.* 17:577-586 ("Bost").

Claim 1 is rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Sharief et al., 1992, *Biochem. Biophys. Res. Commun*. 184:1468-1476 ("Sharief") as evidenced by Roitt et al, 1993, *Immunology*, Mosby, St. Louis, pgs 6.4-6.5 ("Roitt"), and Bost et al., 1988, *Immunol. Invest.* 17:577-586 ("Bost").

Applicant respectfully traverses the rejections as applied to pending claims 27-32.

A. The Present Claims

The present claims are directed to an isolated polypeptide immunologically cross-reactive with human prostatic acid phosphatase, wherein the isolated polypeptide comprises at least 90% amino acid sequence identity to SEQ ID NO:2.

B. The Cited Art

An describes biomarkers for human prostate cancer detected by use of polymerase chain reaction primers based on expressed tag sequences. Polymerase chain reaction is used to determine the relative abundance of particular transcripts in target tissues. From their studies, An provides nucleotide sequences of biomarkers differentially expressed in human prostate cancer, including a marker having approximately 80% sequence identity to SEQ ID NO:2.

Roitt is a general description of antigen-antibody interactions. As characterized by the Patent Office, Roitt is offered to show that when two different antigens share a determinant, antibodies that bind to the determinant of one antigen react with the other antigen.

Bost describes antibodies against a peptide sequence within the HIV envelope protein that also crossreact with human interleukin-2. Bost is offered to exemplify the concept of common determinants and immune crossreactivity described in Roitt.

Sharief describes the cloning of cDNA encoding *human* prostatic acid phosphatase, the genetic structure, and the amino acid sequence of the enzyme.

C. Claims are Novel over the Cited Art

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. The identical invention must be shown in as complete detail as it is contained in the claim." *See Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Moreover, the knowledge must be sufficiently enabling to place the information in the possession of the public. *See In re Omeprazole Patent Litigation*, 82 USPQ2d 1643 (Fed. Cir. 2007).

As an initial matter, the Patent Office's asserted basis of the rejection rests on a claim construction in which the claimed peptide is a form of "human prostatic acid phosphatase" having at least 90% sequence identity to SEQ ID NO:2. In other words, the Patent Office interpretation is that the Applicant is claiming a form of "human prostatic acid phosphatase." Applicant reiterates that this construction is at odds with the descriptions in the specification and the original claims. Nevertheless, with respect to new claim 27, the claim recites an isolated polypeptide which is immunologically cross-reactive with human prostatic acid phosphatase, wherein the isolated polypeptide comprises an amino acid sequence with at least 90% amino acid sequence identity to SEQ ID NO:2. Thus, the claimed polypeptides do not concern isolated human prostatic acid phosphatase, which is shown to have about 80% sequence identity to mouse prostatic acid phosphatase. *See* Specification , page 7, lines 5-10.

As to the substance of the rejection, the Patent Office contends the phrase "an amino acid sequence of SEQ ID NO:2" includes a subsequence of SEQ ID NO:2 of at least four or five amino acids and that a "variant having at least 90% identity to the amino acid sequence of SEQ ID NO:2" refers to any subsequence of SEQ ID NO:2 of ten amino acids wherein at least 9 of those amino acids are identical to SEQ ID NO:2." Yet the basis of the Patent Office's claim construction is not found in the language of the claims or the specification, and appears to arise from an asserted common knowledge in the art that an antibody binds to an epitope of 5 amino acids, and an extrapolation of "90% sequence identity" as meaning a subsequence of 10 amino acids. The examination guidelines, as supported by numerous court decisions, clearly state the impropriety of importing claim limitations that are not part of the claims:

> [I[t is important not to import a claim limitations that are not part of the claim. . . .

See M.P.E.P. § 2111.01; *see also In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("It was incorrect for the Board to read unwritten limitations into claims 13 and 14, limitations contrary to the plain words of the claims, and contrary to

the interpretation that the inventor himself placed on the claims"). Moreover, as emphasized above, the construction is unreasonable since it limits the entirety of the claim based on an antibody reactive with the claimed polypeptide and human prostatic phosphatase while disregarding other portions of the claim. As such, there is nothing within the language of the claims, or even descriptions in the specification, to support the meaning given by the Patent Office. The plain meaning of the instant claims refers to an isolated polypeptide comprising an amino sequence having at least 90% identity to SEQ ID NO:2. The claim does not refer to a subsequence of 5 amino acids or 10 amino acids.

As for the cited art references, An describes a marker expressed in human prostate cancer, where the marker, according to the Patent Office has about 80% sequence identity to SEQ ID NO:2. The instant claims however, recite an isolated polypeptide having at least 90% sequence identity to SEQ ID NO:2. Given the requirement for identity of the elements for a reference to anticipate a claim, An does not anticipate claim 27 or claim 28.

Sharief also does not anticipate the claimed polypeptide since the reference describes human prostatic acid phosphatase, which, as noted in the instant specification, has 80% amino acid sequence identity to SEQ ID NO:2. Therefore, Sharief does not anticipate claims 27 and 28.

Roitt and Bost are not relevant to the anticipation rejection since they describe crossreactivity of antibodies against common determinants between two proteins but do not show any inherent characteristic not disclosed in An or Sharief regarding an isolated polypeptide having at least 90% amino acid sequence identity to SEQ ID NO:2.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §102.

VIII. Conclusion

Claims 27 and 28 are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested. If the Examiner believes that any remaining issues are better resolved by a telephone conference, the Examiner is cordially invited to contact the undersigned at 650-838-4365.

No fees beyond those submitted herewith are believed due in connection with this Amendment. However, the Director is authorized to charge any additional fees that may be required, or credit any overpayment, to Perkins Coie LLP Deposit Account No. 50-2207 (Order No. **57636-8013.US01**).

Respectfully submitted,

Date: August 7, 2007

/ Euk Oh /

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